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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/762,230 | 02/05/2001 | Tadashi Fujii | 2001 0116A | 1705 |

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| EXAMINER | |
|---------------------|--------------|
| FRONDA, CHRISTIAN L | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 12/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|---|--|-------------------------------------|
| <h2 style="margin: 0;">Office Action Summary</h2> | Application No. 09/762,230 | Applicant(s) Fujii et al. |
| | Examiner Christian L. Fronda | Art Unit 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above, claim(s) 11-15 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, and 5-10 is/are rejected.

7) Claim(s) 3 and 4 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

1. Applicants' election of Group I, claims 1-10, and SEQ ID NO: 2 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 11-15 and SEQ ID NO: 1 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The requirement is still deemed proper for reasons of record and is therefore made FINAL.

2. Claims 1-10 and SEQ ID NO: 2 are under consideration in this Office Action.

Claim Objections

3. Claims 2-4 are objected to because of the following informalities: Claims 2-4 are objected to because they recite non-elected subject matter of SEQ ID NO: 1 encoding L-lysine:2-oxoglutaric acid 6-aminotransferase. Applicant is required to cancel the claims or amend the claims to recite the elected subject matter of SEQ ID NO: 2 encoding piperidine-6-carboxylic acid dehydrogenase.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 7, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are directed to all possible DNA containing any gene participating in the production of L-homoglutamic acid, any modifier which hybridizes with said gene, and any DNA encodes any protein having piperidine-6-carboxylic acid dehydrogenase activity. The specification, however, only provides a single representative species encompassed by these claims: a DNA containing the nucleotide sequence of SEQ ID NO:2 encoding a protein having piperidine-6-carboxylic acid dehydrogenase activity. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. The specification does not provide a written description for all possible DNA containing any gene participating in the production of L-homoglutamic acid, any modifier which hybridizes with said gene, and any DNA encodes any protein having piperidine-6-carboxylic acid dehydrogenase activity. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 24, 25, and 30 which depend from claims 21, 27, or 29 are also rejected because they do not correct the defect of claims 21, 27, or 29.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is not clear what specific "DNA containing a gene participating in the production of L-homoglutamic acid" or "modifier which hybridizes with a gene...and has a function capable of recovering the L-homoglutamic acid-producing ability of a mutant" is being claimed as the invention. Claims 7, 9, and 10 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

In claims 5, 6, and 8 the phrase "continuous base sequence from base" renders the claims vague and indefinite because the meaning of the phrase is not known and not defined in the specification. Amending the claims to recite that the claimed DNA contains a nucleic acid sequence consisting of nucleotides 2855 to 4387 of SEQ ID NO: 2 may overcome the rejection.

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Conclusion

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



PONNATHAPURA CHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNICAL GROUP 1600